REMARKS

This Amendment responds to the Office Action dated January 16, 2007 in which the Examiner rejected claims 1, 3-5 and 7-18 under 35 U.S.C. §103.

Claim 1 claims an injection needle and claim 4 claims a liquid introducing instrument comprising an injection needle. The injection needle comprises a puncture section having a needle point capable of piercing a living body, a proximal end section having outside and inside diameters greater than the puncture section, and a tapered section interconnecting the puncture section and the proximal end section. The proximal end section possesses an outside diameter ranging from 0.35 mm to 1 mm, the puncture section possesses an outside diameter ranging from 0.1 mm to 0.5 mm. The length from the puncture section to the tapered section ranges from 0.2 mm to 15 mm. The tapered section possesses an outer profile forming an angle ranging from 0.5 degree to 1 degree and 20 minutes with respect to a line parallel to a central axis of the injection needle. The tapered section provides puncture resistance smaller than the puncture section. The liquid introducing instrument of claim 4 also includes a base body supporting the injection needle, the puncture section of the tapered section protruding from the base body.

Through the structure of the claimed invention having a tapered section provide a puncture resistance smaller than a puncture section and the tapered section possessing an outer profile forming an angle ranging from 0.5 degrees to 1 degree and 20 minutes with respect to a line parallel to a central axis of the injection needle, as claimed in claims 1 and 4, the claimed invention provides an injection needle and liquid introducing instrument comprising the injection needle having a small puncture resistance, and very small flow passage resistance so that the patient

feels little or no pain. The prior art does not show, teach or suggest the invention as claimed in claims 1 and 4.

Claims 1, 3, 4 and 5 were rejected under 35 U.S.C. §103 as being unpatentable over *Gross* (U.S. Patent. 4,781,691) in view of *Melker* (U.S. Patent 5,242,410).

Applicants respectfully traverse the Examiner's rejection of the claims under 35 U.S.C. §103. The claims have been reviewed in light of the Office Action, and for reasons which will be set forth below, applicants respectfully request the Examiner withdraws the rejection to the claims and allows the claims to issue.

Gross appears to disclose provision of an improved needle for performing a spinal anesthesia procedure. (Column 2, lines 55-56). Referring now to FIGS. 2 and 3, there is shown the stepped needle generally designated 10. The needle 10 has a proximal hollow hub 12, and a first elongated tubular portion 14 of a first larger uniform diameter extending distally from and connected to the hub 12. The needle 10 has a second elongated tubular end portion 16 located distal the first tubular portion 14 and being of a smaller uniform diameter than the first tubular portion 14. The needle 10 preferably has an intermediate portion 18 which tapers from the first tubular portion 14 to the second tubular portion 16. The second tubular portion 16 has a beveled tip 20 to facilitate passage of the needle 10 through the body tissue. The second tubular portion 16 has an outer diameter in the range of approximately 0.018 to 0.025 inches, and a respective inner diameter being in the range of approximately 0.010 to 0.017 inches. The minimum length of the second tubular portion 16 is in the range of approximately 1/4 to 3/4 inches to accommodate the thickness of the ligamentum flavum L and dura mater D. (Column 3, line 49 through

column 4, line 1). As shown in FIGS. 2 and 3, a stylet 22 is received in the needle 10, and has an elongated rod 24 extending through the hub 12, the first tubular portion 14, the intermediate portion 18, and the second tubular portion 16. The stylet 22 has a beveled tip 26 which is flush with the beveled tip 20 of the needle 10. As shown in FIG. 9, the rod 24 may have an proximal enlarged first portion 60 with an outer diameter approximately equal to the inner diameter of the first needle portion 14, and a second distal smaller portion 62 with an outer diameter approximately equal to the inner diameter of the second needle portion 16. In this manner, the stylet 22 adds additional strength to the needle 10 during use. In use, the needle 10 is advanced through the body tissue of a patient with the stylet 22 in place until the needle tip 20 passes through the dura mater D and is located in the subarachnoid space S below the spinal cord C. (Column 4, lines 9-26).

Thus, *Gross* merely discloses a tubular portion 16 having a beveled tip 20 and an intermediate portion 18 which tapers. Nothing in *Gross* shows, teaches or suggests the taper section provides puncture resistance smaller than the punch section by having the tapered section possess an outer profile forming an angle ranging from .5 degrees to 1 degree and 20 minutes with respect to a line parallel to a central axis of an injection needle as claimed in claims 1 and 4. Furthermore, nothing in *Gross* shows, teaches or suggests a puncture resistance at the puncture section is 7 gf or less as claimed in new claims 19 and 20. Rather, *Gross* only discloses a tubular portion 16 having a beveled tip 20 and an intermediate portion 18 which tapers.

Additionally, applicants respectfully traverse the Examiner's statement that *Gross* discloses an injection needle capable of piercing a living body. Applicants

respectfully bring the Examiner's attention to column 4, lines 22-26, which discloses that the needle tip in *Gross* is placed into a patient's tissue through a hole made by piercing with a stylet. Since the stylet 22 pierces the body, *Gross* does not show, teach or suggest a needle tip suitable for piercing a living body. Furthermore, the punch resistance at the needle tip in *Gross* would be much larger than a puncture resistance at the puncture section of the claimed invention, since claims 1 and 4 have a needle point capable of piercing a living body.

Melker appears to disclose a wireless high flow sheath introducer for intravascular access and a method for using such an introducer. (Column 1, lines 11-13). As shown in FIG. 1, the wireless high flow sheath introducer set consists of three parts. The innermost part preferably comprises a solid or hypodermic needle 1 approximately 2.5 to 3 inches in length. The needle 1 preferably consists of a stainless steel shaft and the distal end 2 is of course sharpened to medical standards. In the preferred embodiment, the needle 1 includes a connecting hub 3 at its proximal end, such as a plastic Luer-lock hub or other friction fitting connector. In the preferred embodiment, the needle 1 is a 19-gauge hypodermic needle, having an interior diameter (ID) of approximately 0.027 inches and an outside diameter (OD) of approximately 0.042 inches. The second part of the introducer set consists of a dilator 4 which is placed over the needle 1 at the initial stage of insertion, so that the needle 1 is coaxial with the dilator 4. The dilator 4 has an ID slightly greater than the OD of the needle 1, and is tapered at its distal end 5 to form a tight, virtually transitionless fit just proximal to the sharpened distal end 2 of the needle 1. In the preferred embodiment, the distal end 5 of the dilator 4 has an OD of approximately 0.050 inches, widening proximally over approximately one-third of its length to an OD

in the range of about 0.079 to 0.118 inches at a transition point 6. (Column 3, lines 32-56). With the preferred range of dimensions for the introducer set, the degree of taper for the dilator 4 from its distal end 5 to the transition point 6 is preferably in the range of about 1.26° to about 5.18° (a slope of about 0.022 to about 0.09) for a straight-sided dilator 4. This range of slopes has been found to provide a suitable degree of gentle entry into a vessel, while permitting the introducer set to be of reasonable length. In use, the inventive wireless high flow sheath introducer set is used as follows. An appropriate vessel, such as that found in the forearm or antecubital fossa, is located and distended by placing a tourniquet proximal to the insertion site. The site of insertion is cleansed with an antiseptic agent, such as alcohol, and a small nick is made to the skin by means of a scalpel at the insertion site to ease insertion of the intravascular sheath 8. (Column 4, lines 27-46).

Thus, *Melker* merely discloses making a nick in the skin at an insertion site to ease insertion (column 4, lines 38-46). Nothing in *Melker* shows, teaches or suggests a) a taper section provides punch resistance smaller than a punch section, b) a tapered section possesses an outer profile forming an angle ranging from 0.5° to 1° and 20 minutes with respect to a line parallel to a central axis of the injection needle, c) the outside diameter range of the puncture section, d) the length of the puncture section to the tapered section, d) a puncture section having a needle point capable of piercing a living body or e) a puncture resistance at the puncture section 7 gf or less as claimed in claims 1, 4 and new claims 19-20. Rather, *Melker* teaches away from the claimed invention and discloses that the skin must be nicked by a scalpel.

Since nothing *Gross* or *Melker* shows, teaches or suggests a) a tapered section providing puncture resistance smaller than a puncture section as claimed in claims 1 and 4, or b) the puncture resistance at the puncture section is 7 gf or less, as claimed in new claims 19 and 20 or the other features as mentioned above, applicants respectfully request the Examiner withdraws the rejection to claims 1 and 4 under 35 U.S.C. §103 and allows new claims 19 and 20.

Claims 3 and 5 depend from claims 1 and 4 and recite additional features. Applicants respectfully submit that claims 3 and 5 would not have been obvious within the meaning of 35 U.S.C. §103 over *Gross* and *Melker* at least for the reasons as set forth above. Therefore, applicants respectfully request the Examiner withdraws the rejection to claims 3 and 5 under 35 U.S.C. §103.

Claims 7 and 13 were rejected under 35 U.S.C. §103 as being unpatentable over *Gross* in view of *Melker* and further in view of *Hardt et al* (U.S. Patent 5,575,778). Claims 8-11 and 14-17 were rejected under 35 U.S.C. §103 as being unpatentable over *Gross* in view of *Melker* and further in view of *Peery* (U.S. Patent 7,063,681). Claims 12 and 18 were rejected under 35 U.S.C. §103 as being unpatentable over *Gross* in view of *Melker* and further in view of *Kaneko et al* (U.S. Patent 6,517,523).

Applicants respectfully traverse the Examiner's rejection of the claims under 35 U.S.C. §103. The claims have been reviewed in light of the Office Action, and for reasons which will be set forth below, applicants respectfully request the Examiner withdraws the rejection to the claims and allows the claims to issue.

As discussed above, since nothing in the primary references shows, teaches or suggests the primary features as claimed in claims 1 and 4, applicants respectfully

submit that the combination of the primary references with the secondary references will not overcome the deficiencies of the primary references. Therefore, applicants respectfully request the Examiner withdraws the rejection to claims 7-18 under 35 U.S.C. §103.

New claims 19 and 20 have been added and recite additional features. Applicants respectfully submit that these claims are also in condition for allowance, since nothing in the prior art shows, teaches or suggests the puncture resistance at the puncture section be 7gf or less as claimed in new claims 19 and 20.

The prior art of record, which is not relied upon, is acknowledged. The references taken singularly or in combination do not anticipate or make obvious the claimed invention.

Thus it now appears that the application is in condition for reconsideration and allowance. Reconsideration and allowance at an early date are respectfully requested.

If for any reason the Examiner feels that the application is not now in condition for allowance, the Examiner is respectfully requested to contact, by telephone, the Applicants' undersigned attorney at the indicated telephone number to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed within the currently set shortened statutory period, Applicants respectfully petition for an appropriate extension of time. The fees for such extension of time may be charged to our Deposit Account No. 02-4800.

In the event that any additional fees are due with this paper, please charge our Deposit Account No. 02-4800.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

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